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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,129	10/10/2003	Stacey L. Schultz-Cherry	800.039US1	1211

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	**Application No.** 10/684,129	**Applicant(s)** SCHULTZ-CHERRY ET AL.	
	Examiner Benjamin P. Blumel	**Art Unit** 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,12-23,27-32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12-23,27-32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 4, 2006 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(Withdrawn Prior Rejection) Claims 1-7, 9-20, 22, 23, 27-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monroe et al. and Koci et al. further in view of Mueller-Lantzsch et al.

(Withdrawn Prior Rejection) Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Monroe et al., Koci et al. and Mueller-Lantzsch et al. further in view of Kim et al. (WO 92/20803).

(New) Claims 1-7, 12-23, 27-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz-Cherry et al (US 6,696,562 B1), Gulati et al. (Journal of Clinical

Microbiology, 2000), Black et al. (Journal of General Virology, 1993), Koci et al. (Journal of Virology, 2000) and Kim et al. (WO 92/20803).

The instant invention is drawn to a method of identifying an animal exposed to turkey astrovirus-2 (TAstV-2) by contacting blood/serum/plasma samples from the animal (such as a mammal, turkey, chicken or breeder) with a non-denatured TAstV-2 capsid antigen. The capsid antigen is either presented in recombinant, fixed insect cells, which are immobilized onto a substrate (i.e. glass, plastic, a well, etc.) or in a lysate thereof. Bound antibodies (preferably IgM or IgG) are detected by anti-Ig antibodies conjugated to a label, such as a fluorescent molecule, a chromophore, etc. Depending on the label present, various assays can be used to detect the antibody-antibody-antigen complex (i.e. ELISA, RIA or IFA). In addition, the instant invention is also drawn to a kit comprising utilized in diagnosing a TAstV-2 infection.

Schultz-Cherry et al. teach isolation and sequencing of a novel turkey astrovirus, TAstV-2. Schultz-Cherry et al. discuss the use of a TAstV-2 antigen (such as capsid protein) bound to a substrate, which can be utilized to screen biological fluids (i.e. blood, serum, plasma) from a subject for reactive antibodies. This antibody-antigen complex can be screened with a labeled antibody (an enzyme, a fluorescent molecule, etc.) to determine amount of reactive antibodies in the biological fluid. An additional method involves the binding of a TAstV-2 antigen to a bead utilized in a micro-agglutination test for screening biological samples. Schultz-Cherry et al. also disclose that insect cells can be utilized for expressing recombinant TAstV-2 antigens. However, Schultz-Cherry et al. do not teach a specific example working example of the above immunoassays, the presence of IgG or IgM specific for TAstV-2, recombinant insect cells that are fixed to a substrate or a kit for diagnosing a TAstV-2 infection utilizing the above immunoassays.

Gulati et al. teach the screening of turkeys infected with avian pneumovirus (APV) by contacting sera to an immobilized recombinant M protein as part of an ELISA protocol. A total of 184 different specimens were tested, with 133 positive samples.

Black et al. teach the expression of the influenza A M2 protein by insect cells that were fixed by either acetone or 2%-paraformaldehyde treatment.

Koci et al. teach the phylogenic analysis of several Human astroviruses and a novel TAstV-2 based on a predicted capsid protein sequence. This analysis revealed a distinct relationship between these viruses merely based on one common protein.

Kim et al. teach a kit for diagnosing astrovirus infection in human blood by incubating sera with a surface bond recombinant astrovirus antigen. The kit also contains antigens of a broad spectrum of enteric viruses in order to further test human sera samples. Furthermore, Kim et al. disclose that anti-Ig antibodies can be employed to detect either IgM or IgG in the sera.

Koci et al. teach the phylogenic analysis of several Human astroviruses and a novel TAstV-2 based on a predicted capsid protein sequence. This analysis revealed a distinct relationship between these viruses merely based on one common protein.

It would have been obvious to one of ordinary skill in the art to modify the method taught by Schultz-Cherry et al. in order to detect antibodies specific for TAstV-2 capsid antigen, thereby conferring TAstV-2 infection. One would have been motivated to do so, given the suggestion by Schultz-Cherry et al. that the method be screen for immunoglobulins in biological fluids of an infected subject. There would have been a reasonable expectation of success, given the knowledge that sera from turkeys infected with APV was screened for reactive antibodies, as taught by Gulati et al., also given the knowledge that insect cells expressing exogenous proteins (antigens) can be fixed without interfering with antibody-antigen interactions, as taught by Black et al., also given the knowledge that the human astroviruses and TAstV-2 share homology among a key antigen, as taught by Koci et al., and also given the knowledge that the presence of IgM or IgG is indicative of an acute or chronic infection/response, respectively, with regard to human astrovirus infection, in addition to a human astrovirus diagnostic kit for screening human blood comprising a recombinant antigen bound to a substrate and anti-Ig antibodies conjugated to a detectable label, as taught by Kim et al.. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

The declaration under 37 CFR 1.132 filed on December 4, 2006 was reviewed. The arguments by Dr. Stacey Schultz-Cherry that deemed unpersuasive were those of item 4 of the above declaration. The state of the art indicates that the points made in item 4 have been achieved given the teaches of Schultz-Cherry et al., Black et al., Gutali et al. and Kim et al.

Summary

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Benjamin Blumel
Patent Examiner

Bruce Campell

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